REMARKS

The following remarks and the above amendments are submitted to address all issues in this case, and to put this case in condition for allowance. Amendments are made solely to better define the subject matter of the present invention. These amendments are supported by the disclosure of the application as filed and are believed to provide no new subject matter. After the above amendments, application claims 10, 12 and 13 are pending in the application. Application claims 1-9 and 11 are withdrawn. Application claim 10 is the only independent claim.

Applicants have studied the Office Action mailed July 24, 2008 and have the following remarks.

35 U.S.C. 112

First Paragraph

The Examiner has rejected claim 10 under 35 U.S.C. 112, first paragraph, asserting that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with the claims. Specifically, the Examiner asserts that while being enabling for treating COPD, the specification does not reasonably provide enablement for the prevention of the COPD and other acute or chronic diseases because a person of ordinary skill in the art would have to engage in undue experimentation, with no assurances of success, in order to practice the invention.

Without regard as to the correctness of the Examiner's rejection, claim 10 has been amended to remove the term "preventing," mooting the Examiner's rejection of claim 10 under U.S.C. 112, first paragraph.

Second Paragraph

The Examiner has also rejected claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner contends that the phrase "in particular a human" is a narrower statement in the broad range/limitation of "mammals."

Without admission as to the correctness of the Examiner's rejection, claim 10 has been amended to remove the phrase "in particular a human," mooting the Examiner's rejection of claim 10 under U.S.C. 112, second paragraph.

35 U.S.C. 103

The Examiner rejects claim 10 under 35 U.S.C. 103(a) as being unpatentable on two grounds. First, the Examiner rejects claim 10 under 35 U.S.C. 103(a) as being unpatentable over Rothkopf (US 179,080). Second, the Examiner rejects claim 10 under 35 U.S.C. 103(a) as unpatentable over Pouw et al (American Journal of Respiratory Critical Care Medicine, vol 158, 1998, 797-801) in view of Meiji Milk Prod Ltd (EP 0873754). The Examiner is respectfully reminded that, even under the relaxed standards of *KSR*, the Examiner must show each element of the Applicant's claimed invention and sufficient reasoning for a combination in order to make a *prima facie* case for obviousness. Applicant respectfully traverses both of these rejections as the above

references fail to show all the elements of the claims, as amended, and there is no reasonable explanation for modifying the references to obtain the claims as amended.

Rothkopf

The Examiner states that Rothkopf teaches the fact that malnutrition occurs in patients with COPD. The treatment of Rothkopf includes administering to a patient recombinant growth hormone and total parenteral nutrition (TPN). While the Examiner acknowledges that Rothkopf does not teach the instant compositions as a preferred embodiment, the Examiner asserts, without reasoning or explanation, that it would have been obvious to one of ordinary skill in the art to read the teachings of Rothkopf and to realize the need to replace essential and non-essential amino acids, thereby allowing the picking and choosing to supplement the deficient essential and non-essential amino acids.

Applicant respectfully traverses this rejection. Rothkopf's claimed method for treating malnutrition in a patient having chronic lung disease comprises administering recombinant growth hormone in conjunction with TPN. The TPN of Rothkopf comprises different nutrient combinations in different embodiments. In some embodiments of Rothkopf, the TPN may include a certain percentage of protein. The detailed description states that this protein source "*may* comprise mixtures of essential and non-essential amino acids" (emphasis added). In contrast, Applicant's claims are for the treatment of COPD. The composition administered in Applicant's method consists essentially of at least one glutamate, other than mono sodium glutamate, and a precursor of glutamate selected from the group consisting of leucine, valine, isoleucine, and a keto acid thereof.

The Examiner's assertion that Rothkopf renders the Applicant's method obvious is mistaken for three main reasons. First, recombinant growth hormone and TPN are

essential elements of the method of Rothkopf. Recombinant growth hormone and TPN are not essential, or even contemplated, in the composition used in Applicant's method. Second, protein, specifically glutamate and a precursor of glutamate chosen from the group consisting of leucine, valine, isoleucine, and a keto acid thereof are *essential* elements of Applicant's method. These elements are not essential to Rothkopf; they "may" be chosen in one embodiment in which the TPN contains a certain percentage of protein. Third, Rothkopf and Applicant's claims consist of different methods of administration. The method of Rothkopf is administered intravenously. In contrast, the method of Applicant's claims is administered orally.

Furthermore, as a final note, Applicant notes that Rothkopf and Applicant's claims serve completely different purposes. Rothkopf is a method for treating malnutrition, whereas Applicant's claims disclose a method for treating COPD, particularly skeletal muscle fatigue in one embodiment. Taken together, the Examiner is missing the elements of oral administration and a method with the essential elements of Applicant's amended claim. Further, Rothkopf has essential elements (*i.e.,* recombinant growth hormone and TPN) that are not in Applicant's composition used in the method. As such, the Examiner has not, nor can he, account for all of the elements of Applicant's claimed method with the prior art reference of Rothkopf. Further, the Examiner has failed to, and can not, explain and account for how one of ordinary skill in the art would have known of or recognized the missing elements of Applicant's claims from the disclosure of Rothkopf.

Based on the above, Applicant respectfully asserts that the Examiner has failed to show all the elements of Applicant's amended claim with the reference of Rothkopf.

Accordingly, Applicant's claimed method is not obvious in light of Rothkopf and the Examiner is respectfully requested to remove his rejection.

Pouw et al in view of Meiji Milk Prod Co Ltd

The Examiner states that Pouw reports the finding that in patients with COPD, the glutamic acid level in muscles and plasma is decreased, but does not teach treatment of the same. The Examiner attempts to fill in the holes of Pouw et al with Meiji Milk Prod. Co. Ltd., stating that Meiji teaches a composition comprising valine, leucine, isoleucine and glutamic acid, used to supplement for blood amino acids to reduce fatigue after exercise. While the Examiner concedes that Meiji does not teach administration to patients with COPD, the Examiner asserts, without explanation or reasoning, that it would have been obvious to one of ordinary skill in the art to recognize the problem in both references is the lowered amino acid levels and, accordingly, the treatment of the secondary reference may be applied to the disorder of the primary reference as a means of treating COPD.

Applicant respectfully traverses this rejection. As noted by the Examiner, Pouw et al identifies that the glutamic acid level in the muscles of patients with COPD is decreased. However, as also noted by the Examiner, Pouw et al does not disclose any treatment for this condition. Further Meiji Milk Prod. Co. Ltd, the reference used by the Examiner to fill the hole of Pouw et al, only discloses very specific amino acid combinations which comprise no less than 15 amino acids in specified molar ratio ranges for the purpose of supplementing blood amino acids which were diminished during hard exercise to reduce after exercise fatigue. As such, the composition of Meiji Milk Prod. Co. Ltd. consists of amino acids, such as proline and alanine, which are apparently

essential and which are not present in Applicant's claims. The essential elements in Applicant's method are glutamate and a precursor thereof from the group consisting of valine, isoleucine, and a keto acid thereof. The composition of Meiji Milk contains essential elements that are not essential to Applicant's claimed method, and, conversely, Applicant's method contains essential elements which are not essential to Meiji Milk. Further, Pouw et al does not make up for these missing elements and the Examiner has provided no reasoning why the composition used in the present method would be obvious in light of the references. For at least these reasons, Applicant's claims are non-obvious in light of the combination of Pouw et al and Meiji Milk Prod. Co. Ltd. The Examiner is respectfully requested to withdraw his rejection.

Conclusion

In light of the above, Applicant respectfully contends that the pending claims are patentable over the cited art and requests entrance of the above amendments and allowance of all pending claims so that this case can pass on to issue.

As a final point, there is also included herewith a petition for a two month extension of time and the associated petition fee. It is believed no other fees are due in conjunction with this filing; however, the Commissioner is authorized to credit any overpayment or charge and deficiencies necessary for entering this amendment, including any claims fees and/or extension fees to/from our **Deposit Account No. 50-0975**.

Respectfully submitted,
Lewis, Rice & Fingersh, L.C.

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